

### **REMARKS**

Claims 2-8 are pending. Applicants gratefully acknowledge the indication that claims 6 and 7 are allowable.

### **WRITTEN DESCRIPTION REQUIREMENT IS SATISFIED**

Claims 2-5 and 8 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. This rejection is respectfully traversed.

The claims are directed to a method of treating certain conditions, including diabetes, by administering an agent selected from certain compounds and their pharmaceutically acceptable salts. According to the rejection, the specification is allegedly deficient both with respect to the description of the compounds recited in the claims and with respect to treatment of the genus diabetes.

With respect to the recited compounds, relying on Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) and In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967) the rejection, states that “a laundry list disclosure of every possible moiety does not constitute a written description of every species in a genus” (February 12, 2009 Office Action, page 3). The rejection acknowledges that “an applicant may . . . show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e. complete or partial structure. . . .” (February 12, 2009 Office Action, page 3). The original disclosure provides the complete chemical name for each compound recited in the claims. Unlike Fujikawa or Ruschig, there is no need to pick and choose from a laundry list of disclosed moieties in order to arrive at claimed compound species. The chemical names in the original disclosure identify the

chemical structure of such compounds, and thus more than satisfy the written description requirement of Section 112, first paragraph.

With respect to treating diabetes the rejection states, "The mere fact that Applicant may have discovered that type 1 diabetes and type 2 diabetes were effectively treated with the said active agents is not sufficient to claim the entire genus of diabetes, which again includes gestational diabetes." (February 12, 2009 Office Action, page 4).

A reference cited in the September 10, 2007 Office Action identifies the "three major types of diabetes . . . : Type 1 diabetes . . . Type 2 diabetes . . . [and] Gestational diabetes mellitus (GDM). ([www.healthinsite.gov.au/topic/Types\\_of\\_Diabetes](http://www.healthinsite.gov.au/topic/Types_of_Diabetes) (downloaded 8/31/07)). The same reference supports a connection between Type 2 diabetes and gestational diabetes. The reference states, "Risk factors for GDM [gestational diabetes mellitus] include a family history of diabetes, . . . obesity and being a member of a community or ethnic group with a high risk of developing type 2 diabetes." [www.healthinsite.gov.au/topic/Types\\_of\\_Diabetes](http://www.healthinsite.gov.au/topic/Types_of_Diabetes) (downloaded 8/31/07). As seen from the reference, obesity is a risk factor for Type 2 diabetes and for gestational diabetes. Moreover, a family history of diabetes or being a member of an ethnic group with a high risk of developing type 2 diabetes is also a risk factor for developing gestational diabetes.

The Office acknowledges that applicants were in possession of a method of treating type 1 diabetes and type 2 diabetes. In view of the established relationship between type 2 diabetes and gestational diabetes, the original disclosure is sufficient to establish that applicants were in possession, at least, of a method of treating all three major types of diabetes.

Having established that applicants were in possession of a treatment for the three major types of diabetes, it is straightforward to conclude that applicants were in possession of a treatment for diabetes generally. The Office Action explains the standard for written description of a genus as follows:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species . . . .

A “representative number of species” means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure “indicates that the patentee has invented species sufficient to constitute the gen[us].”

(February 12, 2009 Office Action, page 4). In this case applicant has claimed a genus, diabetes. The genus has three major types and applicant has explicitly described two of them, type 1 diabetes and type 2 diabetes. The third type, gestational diabetes, has a known connection to one of the explicitly described types. The Office has failed to establish that there is substantial variation within the genus. And in any event the Office has failed to establish that the described types are not representative of the genus as a whole. Accordingly, the written description is sufficient to show that applicants were in possession of a method of treating the genus diabetes by administering the biologically active agents recited in the claims.

Applicants note that the March 21, 2008 Action rejected claims 2-8 on the same grounds and in virtually the same language. Later, the September 29, 2008 Office Action indicated that “the rejection made under 35 USC 112, first paragraph (Written Description) as set forth in the previous Office Action dated March 21, 2008 at pages 4-6 as applied [to] claims 2-8 is hereby withdrawn because of applicants’ [June 19, 2008] remarks.” As acknowledged by the Office, this rejection constitutes the reinstatement of an old rejection (February 12, 2009 Office Action, page 2, lines 3-4). The February 12, 2009 Action did not explain why the rejection was being reinstated or point to any defect in applicants’ previous arguments. Applicants believe that this rejection has been

overcome. But in the event that the rejection is maintained, then in the interest of either advancing prosecution of this application to allowance or developing the record for appeal, applicants respectfully request that the next Action address applicants' arguments and explain the reasons why the rejection is being maintained.

### **CONCLUSION**

In view of the preceding remarks, applicants respectfully submit that the subject application is in condition for allowance. Applicants respectfully request reconsideration and withdrawal of all rejections, and prompt notice of allowance.

It is believed that no fee is required in connection with the filing of this Communication. If any fee is required, the Commissioner is hereby authorized to charge the amount of such fee to Deposit Account No. 50-1677.

Respectfully submitted,

/Lewis J. Kreisler/

---

Lewis J. Kreisler  
Reg. No. 38522  
Attorney for Applicant(s)

930 Clopper Road  
Gaithersburg, MD 20878  
Phone: (240) 631-2500 x3276  
Facsimile: (240) 683-3794